

**REMARKS**

Reconsideration of the application is requested in view of the remarks below.

**1. Election/Restriction**

Applicants hereby elect the process encompassed by Group I (Claims 1-6).

The election is made without traverse.

**2. Rejection Under 35 USC 112, first paragraph****A. Rejection of Claims 1-6**

The Office Action rejected Claims 1-6 under 35 USC 112, first paragraph, on the grounds that the subject matter "an agent which comprises 1.0 to 3.0 mol of SO<sub>2</sub>" was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

It is basic patent law that when making a rejection under 35 USC 112, first paragraph, the USPTO has the burden to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning. *In re Budnick*, 190 USPQ 422 (CCPA 1976).

Applicants' invention, as encompassed by Claim 1, relates to a "[p]rocess for the preparation of 2-phenylbenzimidazole-5-sulphonic acid, comprising reacting 3,4-diaminobenzenesulphonic acid at a pH between 4 and 7 in aqueous solution with 0.9 to 1.5 mol of benzaldehyde per mole of 3,4-diaminobenzenesulphonic acid and with 1.0 to 3.0 mol of SO<sub>2</sub> per mole of 3,4-diaminobenzenesulphonic acid, or an agent which comprises 1.0 to 3.0 mol of SO<sub>2</sub> per mole of 3,4-diamino-benzenesulphonic acid." Claim 1 claims the use of SO<sub>2</sub> or an agent which liberates SO<sub>2</sub>.

The Office Action states that this is not described or specified in Applicants' application. On page 4, lines 18 - 19 of the application text, the agent liberating SO<sub>2</sub> is described to be "sulphurous acid, preferably in the form of its alkali metal salts, e.g. NaHSO<sub>3</sub>, Na<sub>2</sub>S<sub>2</sub>O<sub>5</sub> or Na<sub>2</sub>SO<sub>3</sub> or SO<sub>2</sub>, also in a gaseous form". The use of Na<sub>2</sub>S<sub>2</sub>O<sub>5</sub> is explicitly described in the example. Reconsideration is requested.

The amount of 1.0 to 3.0 mol of SO<sub>2</sub> mentioned refers to the stoichiometric  
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ratio during use and not to the composition of the salts used as starting compounds. Thus, an amount of 2 mol of 502 per mol of benzaldehyde can be provided both from 2 mol of NaHSO<sub>3</sub> and from 1 mol of Na<sub>2</sub>S<sub>2</sub>O<sub>5</sub>.

B. Rejection of Claims 1-6 under 35 USC 112, first paragraph

The Office Action rejected Claims 1-6 under 35 USC 112, first paragraph, on the grounds that the subject matter does not provide enablement for the use of an agent other than Na<sub>2</sub>HSO<sub>3</sub>, Na<sub>2</sub>S<sub>2</sub>O<sub>5</sub>, or Na<sub>2</sub>SO<sub>3</sub>. The Office Action then goes on to discuss various factors discussed in *In re Wands*, 8 USPQ2d 1400, 1404 (CAFC, 1988). The rejection should be withdrawn.

While the Office Action correctly lists the requirements under *In re Wands*, the Office Action does not apply this case correctly to the facts here.

35 USC 112, first paragraph, requires that the specification contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out the invention.

The specification meets this criteria. The Office Action names Na<sub>2</sub>HSO<sub>3</sub> as an agent. This agent is not mentioned or claimed anywhere in Applicants' application. The Office Action presumably means NaHSO<sub>3</sub>. Other agents apart from those mentioned (Na<sub>2</sub>S<sub>2</sub>O<sub>5</sub> and Na<sub>2</sub>SO<sub>3</sub>) could for example be the salts of other alkali metals and they are also covered by the description. One of ordinary skill in the art would have been immediately aware of this. Reconsideration is requested.

The Office Action's comment on the state of the art is not correct since US 6440401 claims 2-phenylbenzimidazole-di-sulphonic acids: see column 2, formula 1, line 35: "m is 2 or 3"; (The reference referred to describes the production of related products by a different process using arylcarboxylic acid which is considered to be unsatisfactory (sublimation of benzoic acid, see page 1 of the application). This application was referred to since it mentions in column 2, lines 7-11, 2-phenylbenzimidazolesulphonic acid, its salt, its use as a UV filter and the general background to its use in column 1, lines 28-41.

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In addition, in the application text, reference is made to EP 669323 (page 1, lines 18 - 22) as background information (UV radiation, UV-A and UV-B range; skin damage, use of 2-phenylbenzimidazolesulphonic acid as a sunscreen agent).

An important feature is SO<sub>2</sub> or the sulphurous acid H<sub>2</sub>SO<sub>3</sub> obtained therefrom in water or the anion HSO<sub>3</sub><sup>-</sup> obtained therefrom or the anion itself which is entrained by salts of sulphurous acid, since, as discussed, this anion converts benzaldehyde into an aqueous solution (aldehyde/sulphite adducts; elementary chemical knowledge) and oxidizes the intermediate benzimidazoline to form benzimidazole (which is surprising).

The specification contains adequate description of such embodiments. SO<sub>2</sub> is contained in many salts of H<sub>2</sub>SO<sub>3</sub> and this is common knowledge to any chemist. The cation of the salts employed is only relevant in so far as the salt has to be water-soluble. Thus NaHSO<sub>3</sub> is formed from Na<sub>2</sub>S<sub>2</sub>O<sub>5</sub> in water; depending on the pH value, NaHSO<sub>3</sub> and Na<sub>2</sub>SO<sub>3</sub> are jointly present in water. One of ordinary skill in the art would be familiar with SO<sub>2</sub>-liberating salts, so that there is adequate written description supporting scope of the claims. Reconsideration is requested.

The Office Action comments that the specification failed to enable one of ordinary skill in the art to make the invention without undue experimentation is false. The conclusion that an invention cannot be made without undue experimentation is a conclusion reached by considering all of the eight factors: (i) the breadth of the claims, (ii) the nature of the invention, (iii) the state of the prior art, (iv) the level of ordinary skill, (v) the level of predictability, (vi) the amount of direction provided by the inventor, (vii) the existence of working examples, and (viii) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wand*, 8 USPQ2d 1400, 1404 (CAFC, 1988) (See MPEP 2164.01(a)). In this situation, it is clear that the Office Action has not met these requirements. The Office Action does not consider such factors adequately in reach its conclusion. Reconsideration is requested.

Applicants request that the USPTO reconsider its position. The instant specification contains a written description of Applicants' invention, and of the manner and process of making and using it, in such full, clear, concise, and exact

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terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out the invention. Reconsideration is requested.

Double Patenting

The Office Action rejected Claim 2 on the judicially created doctrine of Double Patenting. In view of the enclosed Terminal Disclaimer, the rejection is believed overcome. Reconsideration is requested.

In view of the foregoing amendments and remarks, allowance of Claims 1-6 is earnestly requested.

Respectfully submitted,

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